

Keeping a Laboratory Notebook

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1. WHY MAINTAIN A LABORATORY NOTEBOOK?

It is important to maintain a laboratory notebook to Good Laboratory Practice (GLP) standards because it can be used as a legal document. The lab book can be used to:

- Obtain patents in countries with a “first to invent” system, such as USA, as it proves dates of conception of the invention and reduction to practice.
- Provide evidence of ownership of patents in disputes.

The lab book should contain as much information as possible pertaining to the dates, methods and outcomes of any experimental activities that could result in a patentable invention. Without this documentation it could be difficult to prove in dispute circumstances that either a) you invented first or b) you have the ownership rights to the IP in question.

2. RULES FOR MAINTAINING A LABORATORY NOTEBOOK

In order for a lab book to be viewed as a legal document it must adhere to a number of standards as outlined below:

Book

1. All pages must be bound permanently to the book i.e. no loose leaf pages or spiral bound books.
2. No pages may be removed from the book for any reason.
3. The book must be non-acidic paper.
4. All pages must be consecutively numbered.
5. Different projects should be recorded in different notebooks.
6. A statement should be inserted at the cover or near the front of the notebook stating that the information inside is commercially sensitive and confidential.

Recording entries

1. All entries should be legible.
2. Written in black ink, preferably entries written from the same day should all be recorded in the same pen to avoid allegations that entries were altered at a later date.
3. Avoid leaving large sections blank. Draw a line through any blank sections. This prevents alterations of entries at later dates.
4. Do not use white out or scribble out any mistakes, simply draw a single line through any mistakes leaving them still legible. If it is not obvious why corrections have been made then include a statement outlining the need for the correction.
5. Describe everything in as much detail as required. Clearly state:
 - Pre-experimental data/thoughts/concepts.
 - Purpose.
 - Materials.
 - Methods – and any deviation from.
 - Diagrams.
 - Outcomes/Results.
 - Thoughts for additional steps or research.
6. Include serial numbers of equipment or supplies and the manufacturer, used in the experiment. Also include descriptions of what the equipment is required if it is not obvious.
7. Date and permanently attach any additional information, if it cannot be permanently attached then all witnessing rules still apply and the information should be cross-referenced to the relevant page and notebook.
8. Any results obtained at a later date should be recorded in chronological order and cross-referenced back to the relevant page number that the previous information was entered on.
9. Include details of discussion with other collaborators, lab meetings etc., and who was involved in the discussions.
10. Include reasons why work was put on hold for any extended periods of time, this may be crucial to obtaining patents especially in first to invent systems.
11. Avoid the use of language which indicates the patentability of the experiment outcomes, such as “obvious” or “novel”.
12. All entries should be signed and dated, either at the completion of each page or day. After signing the entry should not be altered in any way.

Witnessing

1. All entries should be witnessed, this is by a person who understands the work and processes being undertaken, but who is not involved in the work. The witness reads the entry then signs and dates it declaring they have thoroughly read and understood the information held within.
2. The witness may be required to verify the work was undertaken in the manner stated in litigation disputes or when attempting to acquire patents.
3. Witnesses should take a photocopy of the witnessed pages and keep these in a place inaccessible to the person in charge of the experiment. This will provide additional support to prove the entries have not been altered post witnessing.

Additional Information

1. Any abbreviations, acronyms and non-standard terms should be defined in a common location at the front of the notebook.
2. A printed version of any witnesses full name should be identified at the front of the notebook, alongside an example

signature, this will allow for easy identification of witnesses if necessary.

3. ELECTRONIC NOTEBOOKS

Currently, electronic laboratory notebooks are not widely accepted in legal proceedings. This is predominantly due to their ease of alterations. For this reason it is suggested that until they are commonly accepted in courts then a hard copy of all information should be maintained.

However, there are a few guidelines that should be adopted if electronic records are to be kept:

- Back-up and write protect all electronic data.
- Store back-ups in an area inaccessible to unauthorised people.
- Reference the data in some handwritten form e.g. a dedicated notebook.
- Use software which prevents editing of original work.
- Ensure security and restrict access to the electronic data e.g. through a password system.

Refer to a patent attorney for more information regarding the legal implications and precautions required for the use of electronic laboratory notebooks.

4. STRUCTURE OF LABORATORY NOTEBOOKS

The following information should be printed on the front of the lab book:

- The organisation name
- The division name
- The laboratory room

- Project name
- Who the lab book belongs to (issued to)
- When the lab book was received (date issued)
- Signature of the lab book owner

- Name of supervisor(s)
- Signature of supervisor(s)

- Book number
- Date the lab book was completed
- The number of the book used before it
- The number of the book to be used after it

- Date the book was stored/archived
- Signature of witness to its storage

Within the first few pages of the book should be:

- Contents with experiment names, dates of entries and corresponding page numbers
- Definitions of Abbreviations and non-standard terms
- Signature samples and printed names for identification purposes

Each page containing experiment entries should include:

Top:

- Experiment title
- Date
- Page continued from (if previous entries had been made concerning the experiment)
- Experiment number

Bottom:

- Name and signature of person who recorded entry
- Supervisor's initials
- Witnesses name and signature
- Dates of all relevant signatures
- Page number the entry record continues on to

5. SOURCES AND HELPFUL RESOURCES

- IP Australia "Practice Good Lab Book Practices" - <http://www.ipaustralia.gov.au/pdfs/ipprof/goodpractices.pdf>